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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB INCORPORATED and BAUSCH & LOMB PHARMA HOLDINGS CORP.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 16-1522(JBS)(KMW)
WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS PHARMA, INC.	)	
Defendants.	)	

ANSWER, AFFIRMATIVE DEFENSES OF WATSON LABORATORIES, INC., ACTAVIS, INC. AND ACTAVIS PHARMA INC., AND COUNTERCLAIMS OF WATSON LABORATORIES, INC.

Defendants Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively, "Defendants"), by and through their counsel, answer the Complaint of Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "Plaintiffs") with the following answers and affirmative defenses, and Watson Laboratories, Inc. further alleges the following counterclaims. Defendants deny all allegations not expressly admitted herein.

THE PARTIES

1. Plaintiff Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same.

2. Plaintiff Bausch & Lomb Incorporated ("B+L") is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application No. 203168, which covers Prolensa®

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same.

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. ("B+L Pharma Holdings") is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same.

4. Upon information and belief, defendant Watson Labs. is a corporation organized and existing under the laws of Nevada, having a principal place of business at 132 Business Center Drive Corona, CA 92880. Upon information and belief, Watson Labs. is a wholly-owned subsidiary of Actavis.

ANSWER:

Defendants admit that Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada. Defendants further admit that Watson Laboratories, Inc. is a wholly-owned subsidiary of Actavis, Inc. Defendants deny the remaining allegations of this paragraph.

5. Upon information and belief, defendant Actavis is a corporation organized and existing under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER:

Defendants admit that Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Defendants deny any remaining allegations of this paragraph.

6. Upon information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis.

ANSWER:

Defendants admit that Actavis Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Defendants deny any remaining allegations of this paragraph.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 9,144,609 ("the '609 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Watson Labs.' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic Bromfenac Ophthalmic Solution 0.07% ("Watson Labs.' generic bromfenac ophthalmic solution").

ANSWER:

Defendants admit that the Complaint purports to state an action arising under 35 U.S.C. §100, et seq., for alleged infringement of United States Patent No. 9,144,609 ("the '609 patent"). Defendants admit that Watson Laboratories, Inc. filed Abbreviated New Drug Application ("ANDA") 206085 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") regulatory approval of a generic version of a 0.07% bromfenac ophthalmic solution. Defendants deny any remaining allegations of this paragraph.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that this Court has subject matter jurisdiction only over claims asserted against Watson Laboratories, Inc. under 35 U.S.C. § 271(e)(2)(A). Defendants deny that this Court has subject matter jurisdiction over any other asserted claims. Defendants deny any remaining allegations of this paragraph.

9. Upon information and belief, this Court has jurisdiction over Watson Labs. Upon information and belief, Watson Labs. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Watson Labs. directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely

destination for the Watson Labs.' generic bromfenac ophthalmic solution. Upon information and belief, Watson Labs. purposefully has conducted and continues to conduct business in this judicial district.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants do not contest this Court exercising jurisdiction over only Watson Laboratories, Inc. for the purposes of this action only. Defendants deny any remaining allegations of this paragraph.

10. Upon information and belief, this Court has jurisdiction over Actavis. Upon information and belief, Actavis is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis directly licenses, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Watson Labs.' generic bromfenac ophthalmic solution. Upon information and belief, Actavis purposefully has conducted and continues to conduct business in this judicial district.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny the allegations of this paragraph.

11. Upon information and belief, this court has jurisdiction over Actavis Pharma. Upon information and belief, Actavis Pharma directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Watson Labs. and/or Actavis, throughout the United States and in this judicial district. Upon information and belief, Actavis Pharma purposefully has conducted and continues to conduct business in this judicial district.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants deny the allegations of this paragraph.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants state that they are not contesting venue in this district as to Watson Laboratories, Inc. for the purposes of this action only. Defendants deny any remaining allegations of this paragraph.

THE PATENTS IN SUIT

13. The U.S. Patent and Trademark Office ("PTO") issued the '609 patent on September 29, 2015. The '609 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '609 patent and have the right to sue for infringement thereof. Senju is the assignee of the '609 patent. A copy of the '609 patent is attached hereto as Exhibit A.

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants admit that Exhibit A appears to be a copy of the '609 patent. Defendants state that the '609 patent speaks for itself, and Defendants deny the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe that patent. Defendants admit that the '609 patent states, on its face, an issuance of September 29, 2015. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of or substantial rights in the '609 patent, and therefore deny the same. Defendants deny any remaining allegations of this paragraph.

14. B+L is the holder of New Drug Application ("NDA") No. 203168 for Prolensa®, which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '609 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

ANSWER:

This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Defendants lack knowledge or information sufficient

to form a belief as to the truth of the allegations concerning ownership of New Drug Application ("NDA") No. 203168, and therefore deny the same. Defendants admit that the United States Food and Drug Administration's website indicates that Bausch and Lomb is the holder of NDA No. 203168 for a bromfenac sodium product, with the proprietary name Prolensa®. Defendants state that the Orange Book speaks for itself, and Defendants deny the allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe the Orange Book. Defendants deny any remaining allegations of this paragraph.

15. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa®.

ANSWER:

Defendants admit that Bromfenac Ophthalmic Solution 0.07% is sold in the United States as Prolensa®, but otherwise deny the allegations of this paragraph.

DEFENDANTS' INFRINGING ANDA SUBMISSION

16. Upon information and belief, Waston Labs. [sic] filed with the FDA ANDA No. 206085, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER:

Defendants admit that Watson Laboratories, Inc. filed with the FDA ANDA No. 206085 under Section 505(j) of the Act. Defendants deny any remaining allegations of this paragraph.

17. Upon information and belief, Watson Labs.' ANDA No. 206085 seeks FDA approval to sell in the United States Watson Labs.' generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

ANSWER:

Defendants admit that Watson Laboratories, Inc. filed ANDA No. 206085 under Section 505(j) of the Act, seeking FDA regulatory approval of a generic version of a 0.07% bromfenac ophthalmic solution. Defendants deny any remaining allegations of this paragraph.

18. Plaintiffs received a letter from Watson Labs. dated February 4, 2016, purporting to be a Notice of Certification for ANDA No. 206085 ("Watson Labs.' notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

ANSWER:

Defendants admit that Watson Laboratories, Inc. sent a letter dated February 4, 2016 concerning Watson Laboratories, Inc.'s ANDA No. 206085 to Bausch & Lomb and Senju Pharmaceutical Co., Ltd. Defendants state that the letter speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the letter. Defendants deny any remaining allegations of this paragraph.

19. Watson Labs.' notice letter alleges that Watson Labs. has submitted to the FDA ANDA No. 206085 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

ANSWER:

Defendants admit that Watson Laboratories, Inc. sent a letter dated February 4, 2016 concerning Watson Laboratories, Inc.'s ANDA No. 206085 to Bausch & Lomb and Senju Pharmaceutical Co., Ltd. Defendants state that the letter speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the letter. Defendants deny any remaining allegations of this paragraph.

20. Upon information and belief, ANDA No. 206085 seeks approval of Watson Labs.' generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa®.

ANSWER:

Defendants admit that Watson Laboratories, Inc. filed ANDA No. 206085 under Section 505(j) of the Act, seeking FDA regulatory approval of a generic version of a 0.07% bromfenac ophthalmic solution. Defendants deny any remaining allegations of this paragraph.

21. Upon information and belief, Watson Labs.' actions relating to ANDA No. 206085 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis and Actavis Pharma.

ANSWER:

Defendants admit that Watson Laboratories is seeking FDA regulatory approval of ANDA No. 206085, and that upon regulatory approval of ANDA No. 206085, Actavis Pharma, Inc. intends to offer to sell and/or sell the products described in ANDA No. 206085. Defendants deny any remaining allegations of this paragraph.

COUNT I

Infringement of the '609 patent under § 271(e)(2)

22. Paragraphs 1-21 are incorporated herein as set forth above.

ANSWER:

Defendants repeat and incorporate by reference their responses to the foregoing paragraphs 1-21 as if fully stated herein.

23. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '609 patent by Watson Labs.' submitting, or causing to be submitted to the FDA, ANDA No. 206085 seeking approval for the commercial marketing of Watson Labs.' generic bromfenac ophthalmic solution before the expiration date of the '609 patent.

ANSWER:

Defendants deny the allegations of this paragraph.

24. Upon information and belief, Watson Labs.' generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

ANSWER:

Defendants deny the allegations of this paragraph.

25. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Watson Labs.' generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

ANSWER:

Defendants deny the allegations of this paragraph.

COUNT II

Declaratory Judgment of Infringement of the '609 Patent

26. Paragraphs 1-25 are incorporated herein as set forth above.

ANSWER:

Defendants repeat and incorporate by reference their responses to the foregoing paragraphs 1-25 as if fully stated herein.

27. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Defendants admit that the Complaint purports to state claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendants deny any remaining allegations of this paragraph.

28. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER:

Defendants admit the allegations of this paragraph as to Watson Laboratories, Inc. only. Defendants deny any remaining allegations of this paragraph.

29. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Watson Labs.' generic bromfenac ophthalmic solution before the expiration date of the '609 patent, including Watson Labs.' filing of ANDA No. 206085.

ANSWER:

Defendants admit that Watson Laboratories, Inc. filed ANDA No. 206085 under Section 505(j) of the Act, seeking FDA regulatory approval of a generic version of a 0.07% bromfenac ophthalmic solution. Defendants deny any remaining allegations of this paragraph.

30. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs.' generic bromfenac ophthalmic solution will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

ANSWER:

Defendants deny the allegations of this paragraph.

31. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs.' generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '609 patent.

ANSWER:

Defendants deny the allegations of this paragraph.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in their prayer for relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

Defendants deny all allegations not expressly admitted herein. Without prejudice to the responses and denials set forth in Defendants' Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses:

FIRST AFFIRMATIVE DEFENSE

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of United States Patent No. 9,144,609 ("the '609 patent") either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the '609 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof.

THIRD AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '609 patent, Plaintiffs are estopped from maintaining that any valid claim of the '609 patent are infringed by Defendants.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against Defendants, in particular any claims asserted by Plaintiffs to the extent such claims allege infringement by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

SEVENTH AFFIRMATIVE DEFENSE

Actavis Pharma, Inc. and Actavis, Inc. are not proper or necessary parties to this suit.

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Complaint, including but not limited to supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Defendant Watson Laboratories, Inc. ("Watson") for its Counterclaims against Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "Counterclaim-Defendants") allege as follows:

1. These are counterclaim actions for declaratory judgment of invalidity and/or non-infringement of one or more claims of United States Patent No. 9,144,609 ("the '609 patent").

THE PARTIES

2. Watson is a corporation organized under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, Plaintiff Senju Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

4. On information and belief, Bausch & Lomb Incorporated is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609.

5. On information and belief, Plaintiff Bausch & Lomb Pharma Holdings Corp. is a corporation organized and existing under the laws of Delaware, with a place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

JURISDICTION

6. This Court has subject matter jurisdiction over these counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Watson and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq*.

7. The Court has personal jurisdiction over Counterclaim-Defendants based on their filing this lawsuit in this jurisdiction and because, on information and belief, Counterclaim-Defendants are doing business in this jurisdiction.

8. Venue is legally proper in this District under 28 U.S.C. §§ 1391 (b) and (c), 28 U.S.C. § 1400 (b) and 21 U.S.C. § 355(j)(5)(C)(i)(II).

ORANGE BOOK LISTINGS

9. On information and belief, on September 29, 2015, the United States Patent and Trademark Office ("PTO") issued the '609 patent, entitled "Aqueous liquid preparation containing 2-amino-3-(4-bromobenzoyl)phenylacetic acid." According to the information on the face of the patent, the patent was assigned to Senju Pharmaceutical Co., Ltd..

10. On information and belief, Bausch & Lomb Incorporated is the holder of New Drug Application ("NDA") No. 203168, directed to PROLENSA®.

11. On information and belief, Counterclaim-Defendants caused the Food and Drug Administration ("FDA") to list the '609 patent, in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NDA No. 203168.

12. By maintaining the listing of the '609 patent in the Orange Book, Counterclaim-Defendants represent that a claim of infringement of the '609 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1)(G).

WATSON'S ABBREVIATED NEW DRUG APPLICATION

13. Watson filed Abbreviated New Drug Application ("ANDA") No. 206085 seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of a generic version of a 0.07% bromfenac ophthalmic solution. In ANDA No. 206085, Watson certified to the FDA that the '609 patent is invalid, unenforceable, and/or will not be infringed by

the manufacture, use, sale and/or offer for sale of Watson's generic version of a 0.07% bromfenac ophthalmic solution.

14. By letter ("Notice Letter") dated February 4, 2016, Watson notified Counterclaim-Defendants that ANDA No. 206085 included a certification that the '609 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Watson's a generic version of a 0.07% bromfenac ophthalmic solution.

15. On March 18, 2016, Counterclaim-Defendants filed an infringement action against Watson alleging infringement of the '609 patent.

16. On information and belief, Counterclaim-Defendants have not caused the FDA to remove the '609 patent from the Orange Book in connection with NDA No. 203168.

17. In light of all the circumstances, there has been and is now an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between Watson and Counterclaim-Defendants as to whether the products described in Watson's ANDA No. 206085 infringe any or all of the claims of the '609 patent and whether any valid claim of the '609 patent exists.

COUNT I

Declaratory Judgment of Invalidity of the '609 Patent

18. Watson repeats and incorporates by reference each of the foregoing paragraphs 1-17 of its Counterclaims.

19. The claims of the '609 patent are invalid for failure to comply with the requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 120, and/or based on other judicially-created bases for invalidation.

20. The alleged invention of the ’609 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

21. The alleged invention of the ’609 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

22. The ’609 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

23. The alleged invention of the ’609 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’609 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’609 patent and would have had a reasonable expectation of success in doing so.

24. The subject matter claimed in the ’609 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

25. The ’609 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

26. The claims of the ’609 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

27. An actual and justiciable case or controversy exists between Watson and Counterclaim-Defendants as to whether the ’609 patent is invalid.

28. Watson is entitled to a declaration that the claims of the ’609 patent are invalid.

COUNT II

Declaratory Judgment of Non-Infringement of the ’609 Patent

29. Watson repeats and incorporates by reference each of the foregoing paragraphs 1-28 of its Counterclaims.

30. Counterclaim-Defendants have accused Watson of infringing claims of the ’609 patent in connection with ANDA No. 206085.

31. Watson denies infringement of any valid, properly construed claim of the ’609 patent, and alleges that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson’s ANDA No. 206085 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the ’609 patent.

32. There is an actual, substantial, and continuing justiciable case or controversy between Watson and Counterclaim-Defendants regarding infringement of the ’609 patent in connection with ANDA No. 206085.

33. Watson is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the products that are the subject of Watson's ANDA No. 206085 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid, properly construed claim of the '609 patent either directly or indirectly.

PRAYER FOR RELIEF

WHEREFORE, Watson prays that the Court enter judgment in its favor and against Plaintiffs as follows:

a) Finding that Watson has not and will not infringe any valid patent claim of the '609 patent;

b) Declaring that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of Watson's ANDA No. 206085 have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '609 patent;

c) Finding that no claim of the '609 patent is valid;

d) Declaring that each claim of the '609 patent is invalid;

e) Granting Watson judgment in its favor on Plaintiffs' claims;

f) Granting Watson judgment in its favor on its counterclaims;

g) Denying Plaintiffs' request for injunctive relief;

h) Dismissing Plaintiffs' Complaint with prejudice;

i) Dismissing Actavis, Inc. and Actavis Pharma, Inc. with prejudice;

j) Finding this case exceptional under 35 U.S.C. § 285 and awarding Watson its costs and reasonable attorneys' fees; and

k) Ordering that Plaintiffs take nothing and otherwise be denied all relief, and that Watson be awarded such other and further relief as the Court may deem just, equitable, and appropriate.

Dated: July 5, 2016

s/ Gregory J. Bevelock
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Attorneys for Defendants
Watson Laboratories, Inc.,
Actavis, Inc, and Actavis Pharma. Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Senju Pharmaceutical Co., Ltd. et al v. Hi-Tech Pharmacal Co., Inc. et al.*, Civil Action No. 16-2270(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al v. InnoPharma Licensing, Inc. et al.*, Civil Action No. 16-1361(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Limited et al.*, Civil Action No. 16-1097(JBS)(KMW), *Senju Pharmaceutical Co., Ltd et al. v. Watson Laboratories, Inc.*, Civil Action No. 15-5591(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al. v. Innopharma Licensing, Inc. et al.*, Civil Action No. 15-3240(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Limited et al.*, Civil Action No. 15-335(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al. v. Innopharma Licensing, Inc. et al.*, Civil Action No. 14-6893(JBS)(KMW) *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd. et al.*, Civil Action No. 14-5144(JBS)(KMW), *Senju Pharmaceutical Co., Ltd. et al. v. Lupin, Ltd. et al.*, Civil Action No. 14-4149(JBS)(KMW), and *Senju Pharmaceutical Co., Ltd. et al. v. Lupin, Ltd. et al.*, Civil Action No. 14-667(JBS)(KMW) are related to the matter in controversy because these suits involve the same New Drug Application. I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, proceeding, or of any pending arbitration.

Executed on July 5, 2016
Madison, New Jersey

/s Gregory J. Bevelock
Gregory J. Bevelock

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration.

Executed on July 5, 2016
Madison, New Jersey

/s Gregory J. Bevelock
Gregory J. Bevelock

CERTIFICATION OF SERVICE

I hereby certify that on the 5th day of July, 2016, I caused the annexed ANSWER, AFFIRMATIVE DEFENSES OF WATSON LABORATORIES, INC., ACTAVIS, INC. AND ACTAVIS PHARMA INC., AND COUNTERCLAIMS OF WATSON LABORATORIES, INC. to be served upon all counsel of record via the Court's ECF system.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on July 5, 2016
Madison, New Jersey

s/ Gregory J. Bevelock
Gregory J. Bevelock